

### **REMARKS/ARGUMENTS**

#### ***Claim Rejections -- 35 USC § 112***

The rejection of claim 1 under 35 U.S.C. 112, first paragraph, is respectfully traversed. The disclosure of non-ionizing radiation in the specification as filed is indeed made in the context of treatment, including killing neoplastic tissue, and not just analysis. The citation that Applicant made in the communication filed 18 December 2006 for the use of non-ionizing radiation is one of several such locations at which non-ionizing radiation is disclosed, all in the section bearing the heading “Full Spectrum Analysis and Treatment” (emphasis added) on pages 22-26, especially pages 22 and 23. The text itself discloses “full spectrum analysis and treatment using electromagnetic energy in all non-ionizing frequencies or wavelengths” at page 22, lines 9-10, and “With even the shortest wavelengths of non-ionizing spectroscopy, analysis and comparison leads to effective therapeutic and sterilization uses” at page 22, lines 15-16 (emphasis added in both quotes). That “treatment” and “therapeutic use” include killing neoplastic tissue is explicitly stated in the same section in paragraph [0077], from which the citation in Applicant’s communication of 18 December 2006 is taken. Thus, there is full support for the recitation of radiation at a non-ionizing wavelength for killing neoplastic tissue in the specification as filed, and claim 1 as amended in the 18 December 2006 communication (and retained herein) is in full compliance with 35 U.S.C. 112, first paragraph.

#### ***Claim Rejections -- 35 USC § 102/103(b)***

The rejection of claims 1-8 both under 35 U.S.C. 102(b) as anticipated by, and under 35 U.S.C. 103(b) as obvious over, Nordquist et al. is once again traversed. The invention is both novel and nonobvious over the disclosure in Nordquist et al. The examiner’s statement “How the radiation effects [*sic*, affects] the tissue cannot be controlled by the cited steps and therefore are [*sic*, is] considered to be an inherent result of the irradiating step” is incorrect. The use of a particular wavelength is indeed part of Applicant’s claimed method, and how the radiation affects the tissue not only can, but is, controlled by the step recited in the claim. Nordquist et al. select a wavelength that is absorbed by the chromophore, while Applicant’s

invention selects a wavelength that is absorbed by neoplastic tissue. These are different selection criteria and different wavelengths. The wavelength selection in Nordquist et al. arises from factors that have nothing to do with proteins and lipids but instead by the absorbance band of the chromophore that is injected, supposedly preferentially, into the neoplastic tissue. This is explicitly set forth in the last paragraph of column 5 and the first paragraph of column 6 of Nordquist et al. The chromophore is neither a protein nor a lipid, as opposed to Applicant's invention in which the selection is based on the specific absorbances of proteins and lipids.

Furthermore, it is not the radiation or the resulting heat in Nordquist et al. that kills the neoplastic tissue, it is the self-immunological defense system that is activated by the heated immunoadjuvant. Applicant's invention does not utilize immunological action to achieve its result.

Still further, the result obtained by Applicant's invention and the result obtained by Nordquist et al. are not the same. The Nordquist et al. method requires that one first identify the locations of the neoplastic tissue to be treated, then inject the chromophore and the immunoadjuvant into these identified locations. The success of this method is limited by the detection sensitivity and extends only to tumors, and even then, only to tumors that are large enough to be detectable. The effectiveness of the Nordquist et al. method does not extend to all areas where the malignant cells have metastasized, and it cannot differentiate between tissue on the basis of the presence of neoplastic character alone but only on the basis of detectability. In many cases, the Nordquist et al. method will not reach all of the neoplastic areas including those that are below the detection limits of a detector. Also, the Nordquist et al. method is not site-specific to the neoplastic tissue, since in regions in which neoplastic cells dispersed among with healthy cells one cannot limit the injection to only the neoplastic cells. Applicant's invention solves both of these problems, and does so by using a different wavelength from that of Nordstrom et al., selected on a different basis.

Aside from the fact that Applicant's method achieves a degree of neoplastic cell destruction that differs from that of Nordquist et al., the fact that the killing of neoplastic tissue to any extent is an "inherent result" of both Applicant's method and the method of Nordquist et

al. does not make Applicant's method either anticipated or obvious. As the CCPA, predecessor of the CAFC, cogently stated in *In re Adams*, 189 USPQ 143 (CCPA 1976):

Finally, the solicitor adds the argument that the *superiority* of appellant's heat transfer is *inherent* in the use of foam. Again we observe that, of course, it is. But the art does not suggest the use of foam in heat transfer of any kind and there is not the slightest suggestion that anyone *knew* of the existence of this inherent superiority until Adams disclosed it. After all, Bell's telephone was "inherently" capable of transmitting speech, DeForest's triode was "inherently" capable of amplification, and to come down to date, so was the tiny transistor which is rapidly cited as supporting the erroneous notion that "subject matter cannot be patented on the basis of an inherent property." We think the proposition thus broadly stated and as applied here is so transparently erroneous as not to require discussion. 148 USPQ at 746. (Emphasis in original)

The beneficial result is inherent in both methods, but even if the degree of benefit were the same (which it is not in this case), achieving any result by one method does not render obvious another method that achieves the same result, where the two methods are distinct and do not suggest each other. Absorption of electromagnetic energy by a chromophore is distinct from absorption of electromagnetic energy by neoplastic tissue, and cell destruction by exposure to excess heat is distinct from cell destruction by immunological defense. In neither case does one suggest, or render obvious, the other.

A further benefit of Applicant's invention is that the killing of neoplastic cells is achieved without the injection of non-native substances into the body, as opposed to Nordquist et al. which requires such injection. The above amendment to claim 1 further clarifies this distinction.

Finally, the examiner's statement that "It is well known in the art to use endogenous chromophores such a [*sic*, as] hemoglobin or porphyrin in the targeting of light therapy in tissue" is not a legally adequate basis for the rejection. The targeting of hemoglobin or porphyrin has nothing to do with neoplastic tissue. Neither of these compounds is specific to neoplastic tissue, nor more concentrated in neoplastic tissue than in healthy tissue, and whatever basis in the art (which has not been identified) the examiner has for this statement, the use of light therapy in general does not render obvious the killing of neoplastic tissue on the basis of a selected wavelength that is specific to the neoplastic tissue and not to healthy tissue.

**CONCLUSION**

With the present amendment and the explanations set forth above, Applicant once again submits that claims 1-8 meet all requirements of 35 USC and are in condition for allowance. Reconsideration of the application is therefore respectfully requested. Should any matters remain that can be resolved by a conference with Applicant's attorney, the examiner is encouraged to telephone the undersigned at 415-576-0200.

Respectfully submitted,



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